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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SHAY, D EXAMINER

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ART UNIT PAPER NUMBER

LAWRENCE M. GREEN
WOLF, GREENFIELD & SACKS
600 ATLANTIC AVENUE
BOSTON, MA 02210

3309

DATE MAILED: 05/16/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on _____ ☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 44-59 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 44-59 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Art Unit 3309

Claims 44-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 10-14 of U.S. Patent No. 4,950,266. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to omit various unclaimed limitations recited in the patent claims and to include the irrigating or transmitting steps which Applicant has discussed as old and well known, thus producing a method such as claimed.

Claims 44-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-20 and 33-35 of U.S. Patent No. 5,196,004. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to omit various unclaimed limitations recited in the patent claims and to include the irrigating or transmitting steps which Applicant has discussed as old and well known, thus producing a method such as claimed.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit 3309

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as now claimed.

Applicant has not disclosed the use of a liquid or of irrigation or of transmitting a fluid to the surgical site.

Claims 44-49 and 53-56 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 47 and 48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47 and 48 are indefinite as it is unclear what further method steps are intended to be claimed by the structure recited.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention

were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 44-59 are rejected under 35 U.S.C. § 103 as being unpatentable over Malyshev in view of L'Esperance ('541). Malyshev teaches a method of performing a surgical procedure by removing tissue using a wavelength in the claimed range. L'Esperance teaches delivering a fluid to a surgical site and the desirability of using an optical fiber to conduct radiation. It would have been obvious to the artisan of ordinary skill to employ an optical fiber in the device of Malyshev since this yields greater flexibility of manipulation, as taught by L'Esperance and to generate the laser beam using a Ho: YAG or Ho: YLF laser, since these are known to produce wavelengths in the claimed range, judicial notice of which is hereby taken and to flush with a liquid, since this is not critical is a well known flushing medium and since it can also be used to cool remaining tissues, judicial notice of which is hereby taken, thus producing a method such as claimed.

Applicant argues that the submitted claims are patentable to Applicant and define the same patentable inventions as the Boutacoff patent. The claims are not patentable to Applicant in view of the above rejections and do not define the claimed invention because the invention resides, at least in part, in the procedure being artherosopic or endoscopic, neither type of

Art Unit 3309

procedure being contemplated by Applicant's disclosure.

Applicant argues that the support for the claims is discussed in the preliminary amendment. The examiner notes that the cited passage on page 15 is concerned with providing a fluid (no mention of a liquid is made) to the probe lens tip area. It is the examiner's perception that Applicant has not disclosed performing surgery on the probe lens tip area. Thus, this cannot be considered to be the surgical site and the claim language is not supported by such a recitation.

Applicant then argues that every limitation of the Boutacoff claims need not be supported by the instant specification. The examiner has never disputed this. However, the patentable limitations therein must be supported by the specification. The instant disclosure and claims do not support the patentable limitation of an endoscopic or artheroscopic procedure and the claims cannot constitute an interference count.

Applicant's arguments that it is not necessary for the Boutacoff disclosures to support each wavelength in the range and that the ranges are not patentably distinct are convincing.

Applicant's arguments that the steps of irrigating while ablating and maintaining a fluid field do not render the Boutacoff claims patentable is noted, but is not convincing. The amendment that resulted in the first notice of allowability to Boutacoff was to add the irrigating step and as set forth on page

Serial No. 049,147

-6-

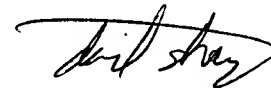
Art Unit 3309

4 of the amendment (paper number 7 of U.S. Application 07/418,942) "the claimed combination of using an infrared laser beam to perform artherosclerotic procedures while irrigating the tissue with a fluid medium" (emphasis added). Thus, while the step in and of itself was previously known, the step in combination with the claimed atherosclerotic procedure is that which yields patentability. Since the irrigating language is necessary to render the claim allowable, claims not including this step cannot be considered to define the same patentable invention as the claims of Boutacoff. Therefore, claims 50-52 and 57-59 do not constitute counts against the Boutacoff claims.

An interference has not been initiated because the claims are not patentable to Applicant and because the claims do not encompass the invention claimed in the Boutacoff.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

D. Shay/dh
May 09, 1994
May 10, 1994
Fax: 703-305-3590/91



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330